UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS NOTICE

50-14

10/10/14

MODERNIZATION OF POULTRY SLAUGHTER INSPECTION: VERIFICATION OF ONLINE REPROCESSING (OLR) AND OFFLINE REPROCESSING (OFLR) ANTIMICROBIAL INTERVENTION SYSTEMS

I. PURPOSE

This notice provides instructions to inspection program personnel (IPP) on how to verify that an establishment's procedures for reprocessing accidentally contaminated poultry using online reprocessing (OLR) or offline reprocessing (OFLR) antimicrobial intervention systems are effective, and that the establishment is meeting regulatory requirements for the use of these systems. This notice also provides two tables that list approved OLR and OFLR antimicrobial intervention systems.

NOTE: The tables listing approved OLR and OFLR antimicrobial intervention systems attached to this notice can be found at http://www.fsis.usda.gov/wps/wcm/connect/4788a166-513f-432c-9e00-f3bcec646558/olr-oflr-tables.pdf?MOD=AJPERES and will be attached to FSIS Directive 7120.1, "Safe and Suitable Ingredients Used in The Production of Meat, Poultry, and Egg Products", in a future revision of the document.

II. BACKGROUND

- A. On August 21, 2014, FSIS published a final rule to modernize poultry slaughter inspection (see *Modernization of Poultry Slaughter Inspection* (79 FR 49565) at http://www.fsis.usda.gov/wps/wcm/connect/00ffa106-f373-437a-9cf3-6417f289bfc2/2011-0012.pdf?MOD=AJPERES. The rule is effective on October 20, 2014.
- B. The final rule amended 9 CFR 381.91 to permit poultry slaughter establishments except for ratite establishments to use approved OLR or OFLR antimicrobial intervention systems to clean carcasses accidentally contaminated with digestive tract contents.
- C. The lists of approved OLR and approved OFLR antimicrobial intervention systems and of the parameters for use of each system are attached at the end of this document as Table 1 and Table 2; respectively.
- D. Under the final rule, establishments are permitted to use OLR and OFLR if FSIS has approved the parameters for use of the antimicrobial intervention system, and the establishment incorporates procedures for OLR or OFLR into its Hazard Analysis Critical Control Points (HACCP) plan or Sanitation standard operating procedures (Sanitation SOP) or other prerequisite program (9 CFR 381.91(b)(1) and (2)).
- E. The final rule amended the regulations to remove the restrictions against using OLR and to remove the requirement that establishments use free available chlorine at 20 ppm to remove visible specks of contamination by OFLR. When the final rule becomes effective, establishments will no longer need a waiver to use approved OLR and OFLR antimicrobial intervention systems.

DISTRIBUTION: Electronic	NOTICE EXPIRES: 11/1/15	OPI: OPPD

III. IPP VERIFICATION RESPONSIBILITIES

- A. At the next weekly meeting, Public Health Veterinarians (PHVs) or Inspector in Charges (IICs) at poultry slaughter establishments, except for establishments slaughtering ratites, are to discuss the information in this notice with the establishment. The PHV or IIC is to document the meeting in a Memorandum of Interview (MOI) in accordance with FSIS Directive 5000.1 Verifying an Establishment's Food Safety System, and provide a copy of the MOI to establishment management.
- B. The effective date of the new OLR and OFLR regulation is October 20, 2014. IPP in establishments that use approved OLR or OFLR antimicrobial systems to reprocess accidentally contaminated poultry carcasses are to follow the instructions in this notice after the final rule becomes effective.
- C. When an establishment uses an OLR or OFLR antimicrobial intervention system to reprocess accidentally contaminated carcasses, IPP are to verify that the antimicrobial intervention system, along with the specific parameters of use, are listed in Table 1 or Table 2. The parameters of use for an OLR or OFLR antimicrobial intervention system may include one or more of the following: the application method, concentration level, pH level, temperature, pressure, and volume of the antimicrobial substance.
- D. If an establishment uses an approved OLR or OFLR antimicrobial intervention system, IPP are to verify that the establishment has incorporated its OLR or OFLR procedures into its HACCP plan or Sanitation SOP or other prerequisite program (also referred to as "the HACCP system").
- E. In the Public Health Information System (PHIS), IPP are to conduct the verification tasks below based on how the establishment has incorporated its procedures in the HACCP system as follows:
 - 1. If the establishment's OLR or OFLR procedures are part of the HACCP plan, IPP are to verify HACCP regulatory requirements by performing, when scheduled by PHIS, the Slaughter HACCP Verification task as outlined in FSIS Directive 5000.1.Chapter III. section II.
 - 2. If the establishment's OLR or OFLR procedures are part of the Sanitation SOP, IPP are to verify that the establishment implements the procedures in its Sanitation SOP and meets all Sanitation SOP regulatory requirements by performing, when scheduled by PHIS, the Operational Sanitation Operating Procedures Review and Observation task as outlined in FSIS Directive 5000.1 Chapter II. section III.
 - 3. If the establishment OLR or OFLR procedures are part of another prerequisite program or other control measure, IPP are to verify the implementation of such program by performing, when scheduled by PHIS, the Slaughter HACCP verification task and following the steps as outlined in FSIS Directive 5000.1 Chapter III. section B. 6.
- F. IPP are to verify that the establishment is properly implementing its procedures for removing visible digestive tract contamination using an OLR or OFLR antimicrobial intervention system by directly observing the establishment's use of the system and reviewing records documenting the establishment's implementation and monitoring of the procedures.
- G. IPP are to verify that the establishment's procedures for OLR and OFLR are effective in removing visible digestive tract contamination by observing the internal and external surfaces of carcasses.
 - 1. For OLR, IPP are to follow the establishment's procedures for observing the inside and outside surfaces of carcasses in a safe manner.

2. For OFLR, IPP are to verify that the establishment makes available reprocessed carcasses for IPP to select a representative sample; e.g. 10 carcasses for inspection before carcasses are returned to production.

NOTE: IPP are to continue to verify the zero tolerance standard for visible fecal material after the final wash and before the chiller but not at the step where carcasses exit the reprocessing systems.

- H. When verifying requirements for OLR and OFLR systems, IPP are to seek answers to the following questions:
 - 1. Does the establishment have procedures for the use of OLR or OFLR incorporated into its HACCP system (i.e. HACCP plan or Sanitation SOPs or other prerequisite program)?
 - 2. Does the establishment's procedure identify the applicable operating parameters for use in the OLR or OFLR system, such as the application method, concentration level, pH level, contact time, temperature, pressure, and volume of the approved antimicrobial substance?
 - 3. Is the establishment implementing and monitoring the OLR or OFLR system as indicated in its procedures?
 - 4. Does the establishment's procedure for an OLR system include:
 - a. instructions to employees to ensure that poultry carcasses that are extensively contaminated or are mutilated (a carcass that is torn apart, shredded, or damaged by slaughter processing equipment) or diseased are removed from the slaughter line so that they do not enter the OLR system, and
 - b. monitoring procedures for carcasses after exiting the system to ensure that the system effectively removes visible contamination from the internal and external carcass surfaces?
 - 5. Does the establishment's procedure for OFLR systems include how the establishment:
 - a. monitors carcasses after completing trimming, washing, or a combination of trimming and washing followed by a chlorine (or other approved OFLR antimicrobial substance) rinse to ensure that the system effectively removes visible contamination from the internal and external carcass surfaces, and
 - b. makes reprocessed carcasses available for FSIS inspection of internal and external carcass surfaces?
- I. When an establishment begins to use an approved OLR or OFLR antimicrobial intervention system or switches from one approved system to another approved system, IPP are to verify that the establishment reassesses and modifies as appropriate the HACCP plan according to 9 CFR 381.22 and 9 CFR 417.4(a)(3).

IV. ENFORCEMENT

- A. IPP are to document in PHIS compliance or noncompliance with 9 CFR 381.91(b) according to the methodology and steps outlined in <u>FSIS Directive 5000.1</u> Chapter V.
- B. Using the appropriate PHIS task based on how the establishment has incorporated its OLR and OFLR procedures into its HACCP system, IPP are to write a Noncompliance Record (NR):

- 1. If the establishment is not properly implementing its procedures, or the procedures do not effectively address visible contamination, e.g., the system results in little or no reduction in contamination, IPP are to issue a NR citing 9 CFR 381.91(b).
- 2. If the establishment does not identify and monitor the operating parameters in the OLR or OFLR system, IPP are to issue a NR citing 9 CFR 381.91(b).
- 3. If mutilated, extensively contaminated, or diseased carcasses enter the OLR system, IPP are to issue a NR citing 9 CFR 381.91(b).
- C. If an establishment has repetitive NRs, or the corrective actions are ineffective, IPP are to discuss with their immediate supervisor the need to take an enforcement action as provided in <u>FSIS Directive 5000.1</u>.
- D. If an establishment wants to use a new OLR or OFLR antimicrobial intervention system that is not listed on Table 1 or Table 2 or to make modification of an approved antimicrobial intervention system, IPP are to inform the establishment that it should submit a notification and protocol for New Technology to the Agency requesting permission to conduct in-plant trials. Information on how to submit a new antimicrobial or modified antimicrobial intervention system can be found in Guidance Procedures for Notification and Protocol Submission of New Technology available on the FSIS web at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/new-technologies/guidance-notification-and-protocol

E. If an establishment is using an unapproved system, IPP are to notify establishment management and take a regulatory control action (RCA) (9 CFR 500.1-.2) to stop the use of the unapproved system because the product may be produced under conditions that preclude FSIS from determining that the product is not adulterated.

V. QUESTIONS

Refer questions regarding this notice to the Risk, Innovations, and Management Staff through <u>askFSIS</u>. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Notice 50-14**

Question Field: Enter question with as much detail as possible.

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **New Technology** from the drop-down menu. Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press Continue and at the next screen press Finish Submitting Question.

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS*, for additional information on submitting questions.

Assistant Administrator

Office of Policy and Program Development

Table 1: List of Approved OLR Antimicrobial Substances

UPDATED 10/17/14

Users of this table should be aware that some of the ingredient mixtures listed may be considered proprietary even though the components are generally recognized as safe (GRAS) notices. As new OLR antimicrobial substances are approved FSIS will update this table by issuing revisions to this notice.

Approved OLR System	Company Name/ Distributor	Substance (antimicrobial) and if applicable, FDA's Food Contact Notification (FCN)	PPM Concentration (range), pH, contact time, temperature (if applicable)	Method of Application (e.g., Spray, Wash, Inside Outside Bird Washer (IOBW) with or without brushes
Accutab Chlorination TM	Southeastern Systems Inc.	Chlorine	20 and 40 ppm, pH between 6 - 7, Citric acid will be used to adjust pH level, 5-10 gallons per minute	IOBW brush cabinet with spray nozzles.
AFCO Peragonn TM	AFCO Safe Foods Corporation	An aqueous solution of Peroxyacetic acid, hydrogen peroxide, and HEDP. FCN 1089	Peroxyacetic acid (not to exceed 220 ppm), 160 ppm for hydrogen peroxide, and 11 ppm for 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP). Delivery pressure of 55-80 psi for a total contact time that can be from 55-65 seconds.	Spray cabinet
Amplon TM formerly AFTEC 3000 (AFT Clear 3000)	Zoetis formerly Advanced Food Technologies	Sulfuric acid, sodium sulfate and water	Fed continuously with tap water dosed with Amplon TM to a target pH of 1.8 +/- 0.4. For spray cabinets, the fresh mixture will be delivered to spray bars at a minimum system pressure of 10 psi and mixture flow between 5 gal/minutes and 10 gal/minute.	Spray cabinet
AVGard®XP	Danisco Inc.	Anhydrous sodium metasilicate (SMS) and Sodium sulfate or sodium carbonated as an anti- scaling agent	SMS rinse applied at a level of 4% +/- 2%	First Spray Cabinet - 20 ppm chlorine Second Spray Cabinet - SMS rinse applied at a level of 4% +/- 2% utilizing drench nozzles at sufficient flow

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Avibrom	Albemarle Corp.	1,3-dibromo-5,5-	AviBrom minimum of	so as to reduce particulate and microbial levels. First Spray
		dimethylhydantion DBDMH	60 ppm and maximum of 100 ppm available bromine; 0.1 gallons of aqueous bromine solution for up to 15 seconds; Flow of water 25 psi pressure and 10 gallons per minute water input.	Cabinet - 60- 100ppm available bromine Second Spray Cabinet - recycled solution used for this cabinet to meet the requirements of water reuse, specifically 9 CFR 416.2(g)
Bio-Cide	Bio-Cide International, Inc.	Acidified sodium chlorite FCN 739	Mixing an aqueous solution of sodium chlorite with any GRAS acid to achieve a pH of 2.2 to 3.0 then further diluting this solution with a pH elevating agent (i.e., sodium bicarbonate, sodium carbonate, or an un-acidified sodium chlorite solution) to a final pH of 5.0 to 7.5. The final sodium chlorite concentration does not exceed 1200 mg/kg and the chlorine dioxide concentration does not exceed 30 mg/kg.	Spray cabinet
CECURE™	Safe Foods Corp	Cetylpyridinium chloride	Cecure spray solution will be diluted with potable water so that CPC concentrations in the final spray, At any particular Cecure spray concentration, the maximum application rate of CPC will not exceed 0.3 grams/pound of	Spray cabinet

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			solution per pound poultry (range from 0.5% to 2.0% solution). For drench applications the concentration shall not exceed 0.8% CPC solution and not to exceed 5 gallons of solution per carcass.	
ChloroSan	Pilgrims' Pride Corporation	Hypochlorous acid solution	10 - 50 ppm with a pH of 2.5 - 7.5	Spray Cabinet
Citrilow TM	Safe Foods Corporation	Citrilow TM , formerly Precure TM , is an aqueous solution of Citric and Hydrochloric acids	pH 1.0 – 2.0, contact time is a minimum 2 seconds.	Spray cabinet
Enviro Tech	Enviro Tech Chemical Services, Inc.	Peroxyacetic acid FCN 887	80-150 ppm PAA and a pH between 3-7	Spray cabinet/ IOBW
FRESHFX L-12	SteriFx, Inc.	A mixture of GRAS acids (citric, phosphoric and hydrochloric) that utilizes low pH to kill pathogens	pH 2.2 or less	Spray cabinet
FreshFX LP	SteriFx, Inc.	A mixture of GRAS acids (citric, phosphoric and sulfuric) that utilizes low pH to kill pathogens	pH of 2.2 or less	Spray cabinet/
Hypochlorous Acid	Tyson Foods	Hypochlorous acid, acidified chlorine	20 – 50 ppm hypochlorous acid solution, pH 5 to 7	Spray cabinet
Hypochlorous acid	TOMCO Equipment Co.	Hypochlorous acid	Not to exceed 50 ppm, contact time minimum of 10 seconds at 5-170 psig	IOBW/brush cabinet system
INSPEXX™ 100	Ecolab, Inc.	An aqueous mixture of peroxyacetic acid, peroxyoctanoic acid, acetic acid, octanoic acid, hydrogen peroxide, and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)	1. PAA Concentration: The PAA concentration is maintained between 20-220 ppm using a single spray cabinet, wash or rinse. 2. Carcass Exposure Time: Carcass exposure to the PAA concentration is a	IOBW/spray wash

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			minimum of 8 seconds. 3. Pressure: Cabinet water pressure is a minimum of 20 psi.	
Inspexx 150	ECOLAB	Peroxyacetic acid (PAA), acetic acid, hydrogen peroxide, and 1- hydroxyethylidene-1, 1- diphosphonic acid (HEDP).	The level of peroxyacetic acid (PAA) is applied at 20-100 ppm.	Spray cabinet/ Wash/IOBW
Microtox 5P	The Vincit Group	Peroxyacetic acid PAA, hydrogen peroxide, 1- hydroxyethylidine-1, 1- diphosphonic acid (HEDP)	PAA: not to exceed 2000 ppm, 750 ppm hydrogen peroxide, and 136 ppm HEDP. Delivery pressure is 10-60 psig.	Spray
Ozone	BOC Gas	An aqueous ozone solution.	Ozone applied at a rate of 3.5 to 4 ppm of ozone at a 3% concentration.	Spray
ProtectFX System	Synergy Technologies	An aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide, acetic acid, and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP). (FCN 1379)	The level of peroxyacetic acid (PAA) not to exceed use concentrations of 2000 ppm, 728 ppm hydrogen peroxide, and 13.3 ppm of HEDP.	Spray cabinet
Sanova	Ecolab Inc., Alcide Corporation	Acidified sodium chlorite	500 to 1200 ppm in combination with any GRAS acid at a level sufficient to achieve a pH of 2.3 to 2.9.	Spray cabinet,
Spectrum®/ Spectrum 2000®	Peroxygens formerly FMC	A aqueous mixture of FCS 323 or FCS 880, peroxyacetic acid, hydrogen peroxide, acetic acid, and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)	18-230 ppm PAA; contact with the antimicrobial treatment solution will be between 3 – 30 seconds.	Spray, IOBW/ brushes
Spectrum® /	Peroxygens	A combination of two	100-2000 ppm PAA;	Spray, IOBW /

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Spectrum 2000®	formerly FMC	aqueous mixtures (FCN 323 or FCN 880), of peroxyacetic acid, hydrogen peroxide, acetic acid, and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)	contact with the antimicrobial treatment solution will be up to 25 seconds.	brushes
Syntrx3200	Synergy Technologies	An aqueous solution of citric and hydrochloric acids adjusted to a pH of 1.0 to 2.0	Applied with a minimum contact time of 2 to 5 seconds measured prior to application.	Spray cabinet
Pathiclean	TOMCO Equipment Co.	A blend of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidine-1, 1-diphosphoric acid (HEDP), and water. (FCN 887)	Peroxyacetic acid not to exceed 220 ppm, hydrogen peroxide, not to exceed 110 ppm, acetic acid, 1-hydroxyethylidine-1, 1-diphosphoric acid (HEDP), not to exceed 13 ppm. Contact time minimum of 10 seconds at 5-170 psig	IOBW/brush cabinet system
Trisodium phosphate		Trisodium phosphate (TSP)	Pre-chill: Applied to carcasses as a spray up to 15 seconds using an 8-12 percent solution. Applied in accordance with good manufacturing practice.(21 CFR 182.1778)	Spray cabinet,

Table 2: List of Approved OFLR Antimicrobial Substances

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AVIBROM (DBDMH)	Albemarle Corp. AVIBROM	1,3-dibromo-5,5 dimethylhydation DBDMH bromine FCN 334 FCN 453	Avibrom 60-100 ppm available bromine; complete coverage of outside and inside of carcass for 60-90 seconds.	IOBW/spray cabinets
Calcium Hypochlorite	N/A	Calcium hypochlorite	20 ppm calculated as free available chlorine Note: Agency guidance has allowed the use of up to 50 ppm calculated as free available chlorine	Spray
CECURETM	Safe Foods Corp	Cetylpyridinium chloride	As a fine mist spray of an ambient temperature aqueous solution applied to raw poultry carcasses, at a level not to exceed 0.3 gram cetylpyridinium chloride per pound of raw poultry carcass, provided that the additive is used in systems that collect and recycle solution that is not carried out of the system with the treated poultry carcasses, or As a liquid aqueous solution applied to raw poultry carcasses prior to chilling at an amount not to exceed 5 gallons of solution per carcass, provided that the additive is used in systems that	Spray

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			recapture at least 99 percent of the solution that is applied to the poultry carcasses. When application of the additive is not followed by immersion in a chiller, the treatment will be followed by a potable water rinse of the carcass.	
Citrilow TM	Safe Foods Corporation	Citric Acid (CA), Hydrochloric acid (HCI), and water.	The application time will not be less than 2 seconds. pH between 1 and 2	Spray
Enviro Tech	Enviro Tech Chemical Services, Inc.	Peroxyacetic acid FCN 887	80-150 ppm PAA and a pH between 3-7	Spray
Inspexx 150	ECOLAB	Peroxyacetic acid (PAA), acetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP).	Inspexx 150 applied at 40-50 ppm PAA.	Spray, Wash or Rinse
Microtox 5P	The Vincit Group	Peroxyacetic acid PAA, hydrogen peroxide, 1- hydroxyethylidine-1, 1- diphosphonic acid (HEDP)	PAA: not to exceed 2000 ppm, 750 ppm hydrogen peroxide, and 136 ppm HEDP.	Spray
PERASAN MP-2	Tyson Foods*	Peroxyacetic acid, hydrogen peroxide, acetic acid, 1- hydroxyethylidene-1, 1- diphosphonic acid (HEDP) and water. FCN 887	PERASAN MP -2 *(Enviro Tech) PAA: 80-150ppm Hydrogen peroxide not to exceed 110 ppm, HEDP not to exceed 13ppm, pH 3.0 – 7.0, contact time between 3 – 30 seconds.	Spray cabinet
PROTECTFX TM 887	SteriFX, ProtecFX	Peroxyacetic acid (PAA) -, hydrogen peroxide, acetic acid, 1- hydroxyethylidene-1, 1- diphosphonic acid (HEDP) and water.	50-100 ppm PAA	Spray

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		Peroxyacetic acid (FCN 887)		
PROTECTFX™ 993	Synergy Technologies	Peroxyacetic acid (PAA) -, hydrogen peroxide, acetic acid, 1- hydroxyethylidene-1, 1- diphosphonic acid (HEDP) and water. Peroxyacetic acid (FCN 993)	Peroxyacetic acid not to exceed 220 ppm	Spray
Sodium Hypochlorite	N/A	Sodium Hypochlorite	20 ppm calculated as free available chlorine Note: Agency guidance has allowed the use of up to 50 ppm calculated as free available chlorine	Spray
Spectrum® / Spectrum 2000®	Peroxygens formerly FMC	A aqueous mixture of FCS 323 or FCS 880,, peroxyacetic acid PAA, hydrogen peroxide, acetic acid, and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)	PAA 18-230 ppm; contact with the antimicrobial treatment solution will be between 3 – 30 seconds.	Spray, , dip tank, IOBW brush cabinet with spray nozzles.